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AUG 4 1995

Robert B. Murray
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Re: Patent Term Extension
Application for
U.S. Patent No. 4,562,073

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,562,073 issued December 31, 1985, which claims the human drug product ZOSYN, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,344 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 30, 1994, as corrected on April 24, 1995. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 \text{ (Testing Phase) } + \text{ Approval Phase} \\ &= 1/2 (1,125) + 781 \\ &= 1,344 \text{ days}\end{aligned}$$


Since the regulatory review period began August 5, 1988, after the patent issue date (December 31, 1985), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The limitations of 35 U.S.C. § 156(g)(6) and the 14 year exception of 35 U.S.C. § 156(c)(3) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,344 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,562,073
Granted:	December 31, 1985
Applicant:	Ronald G. Micetich et al.
Owner of Record:	Taiho Pharmaceutical Company
Title:	PENICILLIN DERIVATIVES
Classification:	424/114
Product Trade Name:	ZOSYN
Term Extended:	1,344 days



Gerald A. Dost
Senior Legal Advisor
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(703) 305-9285

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

RE: ZOSYN
FDA Docket No.: 94E-0071